INTERNATIONAL
SAFETY EQUIPMENT
ASSOCIATION
ISEA

June 1, 2004

Food and Drug Administration
Division of Dockets Management
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville. MD 20852

Re: Comments on Docket Number 80N-145B, Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Proposed Amendment of Final Monograph for Over-the-Counter Ophthalmic Drug Products

Dear Sir or Madam:

The International Safety Equipment Association (ISEA) represents manufacturers of emergency eye wash products and acts as Secretariat to the American National Standards Institute (ANSI) for ANSI Standard Z358.1, the *American National Standard for Emergency Eyewash and Shower Equipment.* ISEA appreciates the opportunity to work with the FDA to ensure that emergency eyewash products are available to the public and are subject to appropriate quality standards. We submit the following information to FDA regarding the May 12, 2003 letter from the American Academy of Ophthalmology.

We understand that the FDA has concern that 21 CFR 200.50 appears to require that all eyewashes be sterile, but does not distinguish between emergency and non-emergency use products. The agency also recognizes that it is impractical in all situations to have sterile eyewash products available. For many emergency situations, a non-sterile preparation is suitable for the irrigation and flushing of the eyes and surrounding skin immediately after the insult occurs, i.e., and before the injured person can receive medical evaluation and treatment.

We believe that the FDA understands that eyewash products can be divided into two distinct and very different product groups for very different applications.

One product is known by the industry as small volume "personal" eyewash, intended for use in the same manner as common over-the-counter eyewash products. These are of smaller volume (32 oz. or less), manufactured under strictly controlled, sterile conditions, and sealed at the time of manufacture.

The other product is a large volume emergency eyewash facility, designed and deployed to effect the rapid irrigation and flushing of an individual's eyes and face after exposure to injurious materials before the injured individual has access to medical treatment.

We believe the agency acknowledges this distinction based on Docket 80N-145B *Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Safety and Efficacy Review* (54 FR 232, December 5, 1989). In this "call-for-information" regarding the ingredients contained in eyewash drug products used for emergency first aid treatment of chemical burns to the eye(s), the sixth paragraph of Supplementary Information states, "The agency is aware that the majority of these products (1) are not intended to be marketed directly to individual consumers; (2) are often packaged in large volume containers not normally found at the retail level of distribution, especially for OTC ophthalmic drug products; (3) may be stored for long periods of time under different environmental conditions; (4) may be marketed in different types of containers and closure systems; and (5) may be used with nonplumbed, plumbed, self-contained emergency eyewash, or shower equipment/stations, etc."

Large volume, emergency eyewash units are designed and installed to permit employer compliance with OSHA's Medical and First Aid Standard, 29 CFR Part 1910.151 which requires, "Where

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the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use." In determining compliance to this requirement, OSHA places reliance on ANSI Standard Z358.1, which establishes minimum performance and use requirements for eyewash and shower equipment for the emergency treatment of the eyes or body of a person who has been exposed to injurious materials. That standard requires that emergency eyewash units be in accessible locations that require no more than 10 seconds to reach.

Large volume emergency eyewash facilities that meet the ANSI Z358.1- standard are designed to be maintained and/or refilled in the field by the end-user. As such, they do not comply with the requirements of 21 CFR 200.50 (a) 3 in that the container (the solution holding tank) is not sterile at the time of filling and closing.

We submit that the nature of these large volume eyewash products is best related to those units defined in 21 CFR 200.50 (b), which describes liquid ophthalmic preparations, packed in multiple dose containers. We believe that properly maintained portable units that meet the standards of this section provide protection equal to plumbed eyewash units, which, by design, are not sterile. While we agree that additives should be free of bacterial contamination, the nature of the product being a high concentration of preservative should preclude the possibility of producing a contaminated solution. Because the end product flushing solution is the result of field preparation, manufacturers cannot ensure flushing fluid sterility, as they do not control the water quality, cleaning, preparation, or mixing technique.

Therefore, we request that you publish recognition that specifically exempts emergency eyewash units from 200.50 (a) (and the comparable device provision, 800.10 (a)) and establishes the following requirements for large volume emergency eyewash solutions and units intended to deliver them:

- Large volume emergency eyewash facilities that meet the ANSI Z358.1standard shall allow for the use of a solution or additive that meets the requirements of this section and shall be packaged with operational instructions for maintenance that will minimize the hazard of injury resulting from contamination.

- Any solution or additive intended for use in emergency eyewash stations shall contain one or more suitable and harmless substances that will inhibit the growth of microorganisms.

- The solution or additive shall be labeled in such a manner as to indicate 1) the manner of preparation and use, 2) the duration of the effectiveness of the preservative under foreseeable conditions of use, and 3) a means of determining and displaying, in a readily visible manner, the expiration date of the mixed solution.

We trust that these provisions address the concerns of the agency, provides for the protection of the public, and will not cause undue burden on commerce and industry.

Sincerely,

Daniel K. Shipp
President